

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed October 12, 2010. Claims 2-5, 7-10, 14-16, and 20-39 were pending and rejected in view of cited art. Claim 10 is canceled and claims 2, 14, 20, 27, and 29 are amended. Claims 2-5, 7-9, 14-16, and 20-39 are now pending in view of the above amendments, of which claims 2, 20, and 29 are the independent claims.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. EXAMINER'S INTERVIEW**

Applicant's express their appreciation to the Examiner for conducting an interview with Applicant's representative on 11 January 2011. The substance of the interview is included in this response.

### **C. CLAIM OBJECTIONS**

The Office Action objected to claim 10 because of certain informalities. By this amendment, dependent claim 10 has been canceled. As such, the objection to claim 10 is moot and Applicant respectfully requests withdrawal of the objection.

### **D. REJECTIONS UNDER 35 U.S.C. § 112**

The Office Action rejected claims 14, 15, 27, and 28 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, while rejected claims

14, 15, and 20-39 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claims 14, 20, and 27 have been amended. In view of the amendments made herein Applicant respectfully requests withdrawal of the rejections under Section 112.

**E. PRIOR ART REJECTIONS**

**I. REJECTION UNDER 35 U.S.C. § 103**

As presented herein for reconsideration (see independent claim 2, as exemplary), the method for delivering a closure element to seal an opening as recited in independent claim 2 includes "inserting a distal end of an elongate member into an opening through tissue". The "elongate member" includes "a distal end, a proximal end, a lumen extending from the distal end to the proximal end, and a skin overlying at least a portion of the outer surface of the elongate member between the distal end and the proximal end and at least partially overlying a carrier assembly slidably disposed on the elongate member and carrying the closure element." The method further includes "deploying one or more medical devices through the lumen of the elongate member."

"[F]ollowing removal of the one or more medical devices from within the lumen" the method includes "*locating a portion of a separate actuator assembly in fluid communication with the lumen of the elongate member* and advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member with the actuator assembly." With this movement, the closure element is advanced "towards the distal end of the elongate member . . . to separate [the skin] from the outer surface of the elongate member" (emphasis added).

Finally, the method includes "engaging tissue adjacent the distal end of the elongate member with a plurality of tissue engaging elements on the closure element" and "withdrawing the elongate member from the opening, thereby leaving the closure element to close the opening."<sup>1</sup>

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<sup>1</sup> The other two independent claims (e.g. claims 20 and 29) are similar.

Claim 20 differs from claim 2 by including, in addition to other elements, "selectively connecting a separate actuating assembly to the elongate member" and "inserting a distal end of an obturator through the lumen of the elongate member *and through a portion of the actuating assembly* and through the opening through tissue" (emphasis added).

Claim 29 differs from claim 2 by including, in addition to other elements, "following removal of the one or more instruments, including the guidewire, *selectively connecting a separate actuating assembly to the elongate*

The Office Action rejected claims 2, 3, 5, 7-10, 16, 29-31, 33, 35, and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,110,184 (*Weadock*) in view of U.S. Patent No. 6,447,540 (*Fontaine*). Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Weadock* in view of *Fontaine* and further in view of U.S. Patent No. 4,596,559 (*Fleischhacker*). Claims 20-26 and 37-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Weadock* in view of *Fontaine* and further in view of U.S. Patent No. 5,674,231 (*Green*). Claim 32 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Weadock* in view of *Fontaine* and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 34 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Weadock* in view of *Fontaine* and further in view of U.S. Patent No. 5,868,755 (*Kanner*). Applicant respectfully traverses.

Applicant respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Weadock* either singly or in combination with any other reference of record.<sup>2</sup> In particular, *Weadock* discloses an introducer “having an integral vascular sealing mechanism” that in turn includes a vessel-engaging component and “a sealing component for effecting closure of the puncture once it has been properly located” (col. 5, ll. 43-44 and 52-53). As described, “[t]he sealing mechanism comprises the applicator 60 and a plurality of thrombogenic rings . . . suspended on the exterior surface 41 of the introducer” (col. 7, ll. 41-44)(emphasis added). As illustrated in Fig. 3B, the applicator includes “a plug having a hole . . . dimensioned so that the applicator 60 may be suspended and slid along the exterior surface 41 of the introducer. Thus, the diameter of the applicator hole 64 should be slightly larger than the diameter of the introducer exterior” (col. 7, ll. 49-53)(emphasis added). Thus, *Weadock* teaches and describes the inclusion of an applicator disposed on the outside of the introducer rather than a separate introducer that is located in fluid communication with the lumen of the introducer. This means that at most, *Weadock*’s introducer includes an applicator or actuator disposed about the “exterior surface 41 of the introducer” and is not in fluid

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*member and locating a portion of a separate actuating assembly in fluid communication with the lumen of the elongate member . . .*” (emphasis added).

Support for these amendments may be found throughout the specification and at least in Figures 6A-6G and the description accompanying Figures 6A-6G.

<sup>2</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

communication with the introducer's lumen and not a separate actuator assembly that is connected to the introducer following removal of the one or more medical devices.

Independent claim 2 recites, in part, "following removal of the one or more instruments, including the guidewire, *locating a portion of a separate actuator assembly in fluid communication with the lumen of the elongate member* and advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member *with the actuator assembly.*" Independent claims 20 and 29 include similar limitations, and specifically recite, in part, and respectively "following removal of the one or more medical devices from within the lumen, *selectively connecting a separate actuator assembly to the elongate member and locating a portion of a separate actuator assembly in fluid communication with the lumen of the elongate member and inserting a distal end of an obturator through the lumen of the elongate member and through a portion of the actuator assembly and through the opening through tissue*" and "following removal of the one or more instruments, including the guidewire, *selectively connecting a separate actuator assembly to the elongate member and locating a portion of a separate actuator assembly in fluid communication with the lumen of the elongate member and advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member with the actuator assembly*" (emphasis added).

No mention is made in *Weaddock* of the "applicator 60" being located in fluid communication with the lumen defined by the "interior surface 43" of the introducer or being a separate applicator that is connected to the introducer "following removal of the one or more medical devices from within the lumen." Rather, and opposite to the method claimed in independent claim 2, the applicator 60 "may be suspended and slid along the exterior surface 41 of the introducer" *id.* Changing the position of the "applicator" and use of the applicator to be in fluid communication with the lumen and locator the "applicator" following "removal of the one or more medical devices" would change the operating principle of *Weaddock* since the applicator is surrounded by a "removable plastic piece or wrap 70" before the introducer is used to provide access. Thus, even if, *arguendo*, one or more of the other cited references disclose disposing an applicator within an introducer, there would be no reason to combine such a teaching because it would inappropriately change the operating principle of *Weaddock*.

Accordingly, for at least the reasons noted, independent claims 2, 20, and 29 and the claims depending therefrom<sup>3</sup> are neither anticipated nor made obvious by *Wedock*, either singly or in combination with any other cited prior art of record<sup>4</sup>, and thus reconsideration and withdrawal of the rejection is respectfully requested.

**F. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

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<sup>3</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 3-5, 7-9, 14-16, and 21-28, and 30-39, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims 3-5, 7-9, 14-16, and 21-28, and 30-39.

<sup>4</sup> *Fontaine*, *Fleischhacker*, *Green*, *Martinez*, and *Kanner*, were cited as secondary references. *Fontaine* was cited for the proposition that it discloses "a skin or sleeve (16) with a weakened region overlying at least a portion of an outer surface between a carrier assembly (20) and a distal end of an elongate member (12) . . ." and "a slippery surface on the sleeve" (Office Action, p. 6). *Fleischhacker* was cited for the proposition that it discloses "the skin (combination 12 and 13) comprising a portion of the skin folded over itself to define a flap (22 and 29) . . ." (Office Action, p. 7). *Green* was cited as disclosing "an obturator with an expandable distal portion", *Martinez* was cited as disclosing "the skin (18) comprising a flap (fingers 51-55) extending generally axially along the outer surface of the elongate member (12) and overlying an adjacent region of the skin . . .", and *Kanner* was cited as disclosing "a skin 1 being bonded to the outer surface of the elongate member by an adhesive . . ." (Office Action, pp. 9-11). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Wedock*. Thus, even assuming *arguendo* that any of the references to *Fontaine*, *Fleischhacker*, *Green*, *Martinez*, and *Kanner* are properly

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Respectfully submitted,

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combinable with *Weadock*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Weadock*.